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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,555	11/12/2003	John W. Mickelson	PC27721A	6894

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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JWA

Office Action Summary

Application No.	Applicant(s)	
10/706,555	MICKELSON, JOHN W.	
Examiner	**Art Unit**	
Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 14-16, drawn to chemical compounds according to Formula I, classified in class/subclass 544/405, 406, 407, 408 and 409.

II. Claims 6-9, 12, 13 and 17-21, drawn to a pharmaceutical composition and methods of treating various conditions, comprising (administering) the compounds provided for above, classified in class/subclass 514/252.1, 255.05 and 255.06.

III. Claims 10 and 11, drawn to methods of screening for ligands for CRF_1 receptors and detecting CRF_1 receptors, respectively, the methods comprising utilizing a compound labeled compound from Group I as set forth hereinabove, classified in, for example, class/subclass 436/501.

The inventions are distinct, each from the other because:

Inventions I and II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case methods of treating, for example, anxiety (recited in claim 18) are known wherein the therapeutic agent is a benzodiazepine compound, which is materially different from compounds according to claim 1. Smoking cessation (recited in claim 18) is practiced with nicotine or bupropion-containing compositions, both of which are also materially different from compounds according to claim 1. Group II is separately classified from Group I, which

is drawn to the compounds *per se*, and for this reason, the pharmaceutical composition, which is classified identically as the methods in Group II, is included in that Group. The search required for determination of patentability of Group II methods and composition is of a different scope than the search required for simple disclosures of chemical compounds. In searching Group II composition and methods, a separate search of the state of the art in at the time the invention was made would be necessary for determination of compliance with the first paragraph of 35 U.S.C. 112.

Invention II is unrelated to invention III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of claims 10 and 11 are not therapeutic; claims 10 and 11 are drawn to *in vitro* methods, and the presence of a labeled compound according to claim 1 is required in those claims, the labeled compounds not being required in the therapeutic methods. Group III is also separately classified, which further demonstrates that it is unrelated to the therapeutic methods in claimed in Group II. Groups II and III are not seen as being commensurate in scope for rejoinder purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate U.S. patent classification, restriction for examination purposes as indicated is proper.

This requirement is further set forth as follows:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This requirement is necessary because the variable "Ar" in claims 1 reads on any aryl, heteroaryl, substituted aryl or substituted heteroaryl ring moiety. As applicants can appreciate, different heterocycles are not obvious variants over one another, and would require separate searches of the chemical literature. The requirement for an

election of species is further necessitated by the widely variable "X" group in claim 1, which includes substantially all types of cyclic groups, heterocyclic and carbocyclic.

The examiner has required restriction between compounds, pharmaceutical compositions, and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined pharmaceutical composition claims and method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, pharmaceutical composition claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §. 804.01.

Information Disclosure Statement

The examiner notes applicant's submission, under 37 C.F.R. 1.97, of the Information Disclosure Statement of 16 April 2004.

The references cited on the accompanying PTO-1449 form are incorrectly cited. 37 C.F.R. 1.98 (b)(5) requires that the relevant pages of a reference be noted in the

citations listed for an Information Disclosure Statement. None of the non-patent literature cited includes the page numbers of the references. Applicant is urged to correct this deficiency, so that the references can properly be considered.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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